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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) ASP0007USA	
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on _____</p> <p>Signature _____</p> <p>Typed or printed name _____</p>		<p>Application Number 09/728,973</p> <hr/> <p>First Named Inventor Nick N. Nguyen</p> <hr/> <p>Art Unit 1797</p>	<p>Filed December 4, 2000</p> <hr/> <p>Examiner Monzer R. Chorbaji</p>
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <div style="display: flex; justify-content: space-between;"><div style="width: 45%;"><p>I am the</p><p><input type="checkbox"/> applicant/inventor.</p><p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p><p><input type="checkbox"/> attorney or agent of record. Registration number _____</p><p><input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 <u>49,082</u></p></div><div style="width: 50%; text-align: center;"> _____ Signature Christian M. Best _____ Typed or printed name 412-355-8636 _____ Telephone number March 11, 2009 _____ Date</div></div> <p><small>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</small></p>			
<p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit 1797	:
	:
Examiner Monzer R. Chorbaji	:
	: Title: VAPORIZER
In re appl. of Nick N. Nguyen et al.	:
	:
Serial No. 09/728,973	:
	:
Filed December 4, 2000	: Confirmation No. 3999

DOCUMENT IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

Applicants respectfully request that the following Document in support of the Pre-Appeal Brief Request for Review be considered at the Pre-Appeal Brief Conference for the above-referenced patent application (the "Subject Application"). A final Office Action for the Subject Application was mailed on December 23, 2008.

Listing of the Claims

The complete listing of the pending claims is illustrated in the Applicants' Amendment dated September 16, 2008, on pages 3 through 9.

Status of the Claims

Claims 1-23 are currently pending in the Subject Application and have been rejected.

Claim Rejections

Independent Claims 9, 13, and 17

The Office Action rejects Independent Claims 9, 13, and 17 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,744,951 to Cummings et al. ("Cummings '951") in view of European Patent Application No. 0 321 908 to Hatanaka et al. ("Hatanaka '908").

Independent Claim 9 recites, among other things, the **method steps of using a vacuum inducing device** to lower the pressure within the vaporizer to **a pressure below atmospheric pressure** and **collecting non-vaporizable components of the sterilant on surfaces forming the circuitous path**. (emphasis added) The combination of Cummings '951 in view of Hatanaka '908 is improper and deficient for at least three reasons.

First, the combination does not disclose or suggest all of the recited claim elements of Independent Claim 9. *In re Wilson* states that, in reference to rejections under 35 U.S.C. §103(a), "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.", 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970), see also, MPEP §2143.03. Neither Cummings '951 nor Hatanaka '908 discloses or suggests the method step of **collecting non-vaporizable components of a sterilant on surfaces forming the circuitous path**, let alone in a **sub-atmospheric environment**.

Second, the teachings of Cummings '951 in view of the teachings of Hatanaka '908 are in direct contradiction to one another, let alone the claimed vaporization method of Independent Claim 9. A prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). In short, Cummings '951 teaches a vaporization system which draws water vapor out of a vaporized hydrogen peroxide solution to **increase the concentration** of the vaporized hydrogen peroxide solution prior to flowing the vaporized solution into a sterilization chamber (see Cummings '951, Abstract). On the contrary, Hatanaka '908 discloses **admitting a hot carrier gas into a vaporizer** (see Fig. 2) such that the hot carrier gas can be mixed with a vaporized hydrogen peroxide solution (see Hatanaka '908, col. 3, lines 4-14). Applicants submit that the admission of the hot carrier gas into the vaporizer of Hatanaka '908 **deceases the concentration** of the vaporized hydrogen peroxide solution before the vaporized solution is introduced into a sterilization chamber, which is in direct contradiction with the teachings of Cummings '951. Further, Applicants respectfully submit that the influx of the hot carrier gas of Hatanaka '908 into the vaporizer will, if anything, **increase the pressure within the vaporizer** instead of operating the vaporizer **at a pressure below atmospheric pressure** and, as a result, **it is clear** that Hatanaka '908 teaches away from the claimed invention.

Third, the combination of Cummings '951 in view of Hatanaka '908 changes the principle of operation of the Cummings '951 device, contrary to the instructions provided in MPEP. The MPEP specifically instructs that "[i]f the proposed modification or combination of the prior art would **change the principle of operation of the prior art invention** being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." (emphasis added) MPEP § 2143.01, see also, *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959). Applicants submit that the combination of Cummings '951 in view of Hatanaka '908 changes the principle of operation of Cummings '951, the primary reference. The principle of operation of Cummings '951 is to **increase**

the concentration of hydrogen peroxide within a hydrogen peroxide solution by drawing water vapor out of the hydrogen peroxide solution. As a result, this primary principle of operation of Cummings '951 is defeated when combined with Hatanaka '908's vaporizer, as Hatanaka '908 teaches to **decrease the concentration of hydrogen peroxide** within a hydrogen peroxide solution owing to **the influx of the hot carrier gas** (*i.e.*, super-atmospheric conditions).

By not performing its vaporization at a pressure below atmospheric pressure, Hatanaka '908 cannot achieve at least three benefits of the claimed invention. First, vaporization at a sub-atmospheric pressures can provide a margin of safety should a leak develop anywhere in the vaporizer. In the event that the claimed vaporizer were to develop a leak, air would rush into the system at the leak, as opposed to sterilant vapor rushing out as would likely occur in the vaporizer disclosed in Hatanaka '908. Sterilant vapors leaking out of a vaporizer may have various undesirable consequences. Second, it is often important to at least partially remove the air, or other gases, from within the vaporizer prior to or during the vaporization process because these gases may lead to ineffective sterilization and/or contamination within the vaporizer. The claimed vaporizer not only removes these gases, but also removes at least a portion of the non-vaporizable components of the sterilant to reduce the possibility that these non-vaporizable components will be deposited on various devices being sterilized. Third, the sub-atmospheric conditions provided by the claimed vaporizer can aid in the diffusion of sterilant vapor into long, narrow lumens of various devices being sterilized leading to a more efficient sterilization process. Under super-atmospheric conditions, as taught in Hatanaka '908, the sterilant vapor is, to some extent, inhibited from entering and sterilizing these long, narrow lumens, owing to the positive pressure within the lumens.

Therefore, Applicants respectfully submit that for at least the reasons advanced above, Independent Claim 9, and the claims depending therefrom, should be allowed. Independent Claims 13 and 17 recite similar recitations as Independent Claim 9 and, therefore, for analogous reasons, Independent Claims 13 and 17, and the claims depending therefrom, should also be allowed. Applicants have not amended the claims and, therefore, **no new search should be required**.

Independent Claims 1 and 5

Independent Claim 1 recites, among other things, a vaporizer comprising a **removable core including a circuitous path**, wherein the **circuitous path is configured to collect a first portion of non-vaporizable ingredients of the sterilant**, a flow restriction configured to cause a **second portion of the non-vaporizable ingredients to collect on a surface of the vaporizer** prior to the vapor phase sterilant being admitted to a sterilization chamber, and a **vacuum pump** configured to create a

vacuum within the circuitous path. (emphasis added) Independent Claim 5 includes similar recitations as Independent Claim 1 and also comprises, among other things, the recitation of a flow restriction comprising an orifice, wherein the orifice includes a cross-sectional area **no greater than 44.1%** of a cross-sectional area of the circuitous path immediately upstream of the orifice. (emphasis added)

In addition to the above-discussed deficiencies, neither Cumming '951 nor Hatanaka '908 discloses or suggests a **removable core, collecting non-vaporizable ingredients of a sterilant**, or an orifice including a **cross-sectional area no greater than 44.1%**. In fact, neither Cummings '951 nor Hatanaka '908 discloses or suggests collecting non-vaporizable ingredients of a sterilant **at all**, let alone in a **sub-atmospheric environment**. As a result, the Applicants submit that the 35 U.S.C. §103(a) rejections of Independent Claims 1 and 5 are based solely on impermissible hindsight. As stated in §2142 of the MPEP:

The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight **must be avoided** and the legal conclusion must be reached on the **basis of the facts gleaned from the prior art**.

MPEP §2142 (emphasis added), *see also, In re Deminski*, 796 F.2d 436, 443 (Fed. Cir. 1986).

For at least the reasons advanced above, the Applicants respectfully request withdrawal of the 35 U.S.C. §103(a) rejections of Independent Claims 1 and 5, and the claims depending therefrom, and request allowance thereof at an early date. Applicants have not amended the claims and therefore **no new search should be required**.

Independent Claim 21

The Office Action rejects Independent Claim 21 under 35 U.S.C. §102(b) as being anticipated by Hatanaka '908.

In evaluating the patentability of claims under 35 U.S.C. §102, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference". *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). As a result, an **Examiner cannot simply ignore** a recited element of a claim because it is **configured**, structured, arranged, or adapted to have a particular characteristic **as such language imparts a structural recitation**. (emphasis added) *See e.g., Application of Venezia*, 530 F.2d 956, 960 (C.C.P.A. 1976). Hatanaka '908 does not disclose or suggest all recitations of Independent Claim 21 for at least the following reasons.

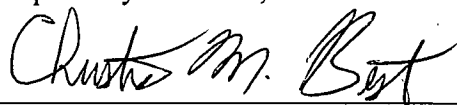
First, Hatanaka '908 does not disclose or suggest "a core configured to be at least partially positioned within the inner space and removed from the inner space". In an attempt to "locate" this claimed recitation, the Examiner cites col. 4, lines 43-46 of Hatanaka '908, which states "[f]urthermore, the apparatus is compact enough as an evaporation means and it can easily be demounted in respect to maintenance and therefore has high high (sic) economical effect." (see Office Action p. 2). Nothing in this passage of Hatanaka '908 discloses, teaches, or suggests that elements 7, 9, and 10 comprise a core that can be removed from housing 2, as argued by the Examiner and, therefore, the 35 U.S.C. § 102(b) rejection must be withdrawn. Applicants have not amended the claims and, therefore, **no new search should be required**.

Second, Hatanaka '908 does not disclose or suggest "the circuitous flow path is configured to cause the vaporized liquid sterilant to deposit a first portion of the non-vaporizable components on at least one of the fins and the housing" or "the first portion of the outlet tube is configured to be positioned proximate to the closed end of the recess to create a flow restriction for the vaporized liquid sterilant and thereby cause a second portion of the non-vaporizable components to deposit one of the walls of the recess and the outlet tube". Not a single passage in Hatanaka '908 discloses or suggests depositing non-vaporizable components of a sterilant and, therefore, the 35 U.S.C. § 102(b) rejection must be withdrawn. Applicants have not amended the claims and, therefore, **no new search should be required**.

Conclusion

Applicants respectfully submit that all of the claims presented in the Subject Application are in condition for allowance. Applicants' present response should not in any way be taken as acquiescence to any of the specific assertions, statements, etc., presented in the Office Action not explicitly addressed herein. Applicants reserve the right to specifically address all such assertions in their Appeal Brief if such is filed.

Respectfully submitted,



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